Section E. 510 (k) Summary of Safety and Effectiveness

(The following information is in conformance with 21 CFR 807.92.)

Date Prepared April 04, 2000

Establishment Name and Registration number of submitter

Name: SMV America
8380 Darrow Road
Twinsburg, Ohio 44087

Registration number: 1528274

Contact: Francois Roche

Device name and classification

Classification Code: 90 KPS

Panel Identification: Radiology

Proprietary Name: POSITRACE™

Common Name: Combined PET/CT imaging System

Classification Name: System, Emission Computed Tomography

Classification Class: Class II Product

Reason for 510(k) submission New Device

Predicate device (K972686) 90KPS, VCAR
SMV
(K991841) KPS, HAWKEYE
ELGEMS, LTD.
(K973396) KPS, QUEST PET IMAGING SYSTEM
UGM MEDICAL SYSTEM
Anatom 2000. K944131 (CT Scanner)

Device Description

POSITRACE™ combines whole-body positron emission tomography (PET) scanning with a diagnostic quality computed tomography (CT) scanner, POSITRACE™ is intended for use as a diagnostic imaging device. Used with appropriate radiopharmaceuticals, it produces images, which depict the anatomical distribution of radioisotopes within the human body. The integrated CT system is intended to provide an enhancement to the emission images by compensating for the attenuation effects of the human body, it will also provide registration of anatomical and physiological images to localize the radioisotope activity in the patient anatomy.

The PET module is a ring design which uses 6 rectangular NaI(Tl) scintillation crystal. It provides a 50 cm axial field of view for whole body coverage and a 70 cm patient aperture.

The CT is capable of low resolution imaging for attenuation correction and high resolution imaging for anatomical localization of the radioisotope activity.

POSITRACE™ provides a user interface, which integrates and takes into account the specificity of the two modalities.

Intended Use

POSITRACE™ combines whole-body positron emission tomography (PET) scanning with a diagnostic quality computed tomography (CT) scanner, POSITRACE™ is intended for use as a diagnostic imaging device. Used with appropriate radiopharmaceuticals, it produces images which depict the anatomical distribution of radioisotopes within the human body. The integrated CT system is intended to provide an enhancement to the emission images by compensating for the attenuation effects of the human body. It will also provide registration of anatomical and physiological images to localize the radioisotope activity in the patient anatomy.

Technological Comparison

POSITRACE™ combines two imaging modules, PET and X-Ray CT.

The PET module is similar to VCAR and to the QUEST PET. It is similar in the intended use and similar in the techniques and algorithms used to provide nuclear medicine PET images. The primary difference when compared with the predicate system, QUEST PET, is that POSITRACE™ provides a greater field of view (50 instead of 25 cm), greater aperture (70 instead of 58 cm), and integrates a diagnostic CT module.

The CT imaging intention of use is similar to the HAWKEYE for attenuation correction and anatomical localization. The primary differences are (a) HAWKEYE is an addition to a general purpose gamma camera (Millennium VG) where POSITRACE™ is based on a dedicated PET imaging system, and (b) POSITRACE™ offers the ability to produce clinically useful CT images.

Testing

Major performance parameters have been measured using industry-standard test methods to determine that the device meets its specifications and performs in a fashion similar to predicate devices.

Clinical and non-clinical studies were conducted using 2 POSITRACE™ units. Images and physical measurements produced demonstrate that POSITRACE™ (PET images and CT images for attenuation correction and anatomical localization) were of the same quality as those provided by the manufacturers of the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 25 2000

Mr. Francois Roche
SMV America
8380 Darrow Road
Twinsburg, OH 44087

Re: K001681
POSITRACE™ Dual Mode
PET/CT Oncology System
Dated: May 24, 2000
Received: June 1, 2000
Regulatory Class: II
21 CFR §892.1200/Procode: 90 KPS

Dear Mr. Roche:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure(s)

Section F. Indications for Use Form

510(k) Number (if known): K001681

Device Name: POSITRACE™

Indications For Use:

POSITRACE™ combines whole-body positron emission tomography (PET) scanning with a diagnostic quality computed tomography (CT) scanner, POSITRACE™ is intended for use as a diagnostic imaging device. Used with appropriate radiopharmaceuticals, it produces images, which depict the anatomical distribution of radioisotopes within the human body. The integrated CT system is intended to provide an enhancement to the emission images by compensating for the attenuation effects of the human body, it will also provide registration of anatomical and physiological images to localize the radioisotope activity in the patient anatomy.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K001681

(Optional Format 3-10-98)